

## REMARKS

### Application Amendments

By the amendments presented Claims 1-2, 7-11, and 41-42 have been rewritten to more particularly and distinctly claim the subject matter that Applicants regard as their invention.

Support for the amendments is found in Applicants' original Claims 1-20, in the Specification at Page 6, Lines 9-12; and, in the Specification at Page 34, Lines 4.

Attached hereto is a marked-up version of the changes made to the claims by current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

Upon entry of the amendments presented, Claims 1-19 and 41-54 remain in the application. No additional claims fee is believed due as a result of these amendments. Authorization, however, is given in the cover sheet to charge any fee due to the Assignee's deposit account.

## REMARKS

### Invention Synopsis

The present invention is directed to flowable nondigestible oil compositions comprising a liquid polyol fatty acid polyester having a complete melt point of less than about 37° C., and a crystallized solid polyol fatty acid polyester having a complete melt point of at least about 37° C. The solid polyol fatty acid polyester comprises a plurality of crystallized particles which preferably includes a solid saturated polyol polyester, within the liquid polyol fatty acid polyester. The flowable, nondigestible oil compositions have a Consistency (K) within the temperature range of 20° C to 40° C of less than about 50 P·sec<sup>(n-1)</sup>. The compositions of this invention are capable of being handled and stored in a flowable state at room and ambient storage temperatures, thereby avoiding exposure of the compositions to high temperatures (generally greater than 50° C.) which would otherwise be required to make such compositions flowable. The ability to use ambient handling and storage conditions for the compositions herein tend to minimize the effects of heat and high temperatures on the chemical stability of the polyol fatty acid polyester, which results in greater oxidative stability and flavor stability

during extended storage of both the nondigestible oil compositions herein and the food products containing the nondigestible oil compositions.

The present invention is also directed to a process for making flowable nondigestible oil compositions. The process comprises the steps of (1) completely melting the nondigestible oil composition containing the solid polyol fatty acid polyester and the liquid polyol fatty acid polyester, (2) crystallizing the solid polyol polyester into a plurality of crystallized particles, preferably in two crystallization steps or stages; and (3) shearing the polyol polyester composition during the step of crystallizing the solid polyol fatty acid polyester.

#### Formal Matters

Claims 1-19 and 41-54 have been rejected under 35 U.S.C. §112, First Paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner contends that Applicants' claim elements of a Consistency in the temperature range of 20° C to 40° C of less than about 30 P·sec<sup>(n-1)</sup>, is not supported by Applicants' disclosure of Consistency in the temperature range of 20° C to 40° C of less than about 1000 P·sec<sup>(n-1)</sup>. Applicants respectfully traverse this rejection.

The first paragraph of 35 U.S.C. §112 requires that the "specification shall contain a written description of the invention." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Applicant(s) can demonstrate possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention as is required. See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis. See *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972), stating that "precisely how close [to the claimed invention] the description must come to comply with Sec. 112 must be left to case-by-case development.". See also, *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96, stating that inquiry is primarily

factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.

To comply with the written description requirement of 35 U.S.C. §112, first paragraph, each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim “is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.” *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998). See also *In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989).

Applicants assert that the Specification and claims as originally filed provide ample written support for the amended claims, in that the description of “a Consistency in the temperature range of 20° C to 40° C of less than about 100 P<sup>n-1</sup>sec” (i.e., read and understood as “being in the range of from about 0 P<sup>n-1</sup>sec to about 100 P<sup>n-1</sup>sec”) “expressly, implicitly, and inherently contains the range of “a Consistency in the temperature range of 20° C to 40° C of less than about 30 P<sup>n-1</sup>sec” (i.e., read and understood as “being in the range of from about 0 P<sup>n-1</sup>sec to about 30 P<sup>n-1</sup>sec.””

With respect to amending numerical range limitations specifically, the analysis of the sufficiency of the written description must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of “25%-60%” and specific examples of “36%” and “50%.” A corresponding new claim limitation to “at least 35%” did not meet the description requirement because the phrase “at least” had no upper limit and caused the claim to read literally on embodiments outside the “25% to 60%” range, however a limitation to “between 35% and 60%” did meet the description requirement.

In the instant case, the original Specification and claims disclosed the range of from about 0 P<sup>n-1</sup>sec to about 100 P<sup>n-1</sup>sec, within the temperature range of 20° C to 40° C. Applicants assert, therefore, that as in *In re Wertheim* the limitation of from about 0 P<sup>n-1</sup>sec to about 30 P<sup>n-1</sup>sec, within the temperature range of 20° C to 40° C, which is contained within the originally disclosed range, meets the written description requirement.

Applicants also assert that in addition to the amended ranges being expressly, implicitly, and inherently supported by the original Specification and claims, the ordinarily skilled artisan would readily understand that the amended ranges currently claimed (e.g., “a

Consistency in the temperature range of 20° C to 40° C of less than about 30 P·sec<sup>(n-1)</sup>) are clearly supported by Applicants' originally disclosed range of "a Consistency in the temperature range of 20° C to 40° C of less than about 100 P·sec<sup>(n-1)</sup>." The range of "less than about 30 P·sec<sup>(n-1)</sup>," being interpreted by one of ordinary skill in the art as the range of from about 0 P·sec<sup>(n-1)</sup> to about 30 P·sec<sup>(n-1)</sup>, is clearly contained within the range of "less than about 100 P·sec<sup>(n-1)</sup>," being interpreted by the ordinarily skilled artisan as the range of from about 0 P·sec<sup>(n-1)</sup> to about 100 P·sec<sup>(n-1)</sup>. It is well understood by one of ordinary skill in the art that the use of a numeric range to indicate the value of a given variable is not intended to be limited to just the end points of that stated range. The ordinarily skilled artisan will appreciate that the use of a numeric range to indicate the value of a variable is meant to include not just the values bounding the stated range, but also all values and sub-ranges contained therein. As such, Applicants respectfully assert that the rejection is in error and should be withdrawn.

Moreover, in matters relating to the sufficiency of the written description in supporting amended claims, the Examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. See MPEP §2163(II)(A)(3)(b). Also, see *In re Wertheim*, 541 F.2d at 263, 191 USPQ at 97, stating that "[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." In the instant case, however, the Examiner has provided no such reasoning or rationale. Here the Examiner has simply stated only that the claims as amended are not supported, and nothing more. Applicants respectfully assert, therefore, that the Examiner's rejection of insufficient written support is insufficient as a matter of law, and therefore the rejection is improper and should be withdrawn.

#### Art Rejections

Claims 1-19 and 41-54 have been rejected under 35 U.S.C. §103(a) as unpatentably obvious over Elsen et al. (U.S. Patent No. 5,422,131). The Examiner contends that it would have been "obvious to one of ordinary skill in the art having the Elsen et al patent before him to obtain the instant claimed nondigestible composition in view of their closely related structures and the resulting expectation of similar organoleptic properties for food prepared with the nondigestible compositions." Applicants respectfully traverse this rejection.

As acknowledged by the Examiner, the nondigestible composition encompassed by the instant claims "differ from the nondigestible composition disclosed in the Elsen et al reference in the recitation of the compositions having 'a Consistency in a temperature range of 20-40°C of less than about 600 P.sec <sup>(n-1)</sup>", which is not recited in the Elsen et al. patent." The Examiner incorrectly states, however, that "this difference does not appear to be of patentable moment and may be within the scope of the nondigestible composition of the Elsen et al patent."

The Elsen et al patent discloses a nondigestible fat composition which, though comprised of a liquid component and a solid component, is substantially solid at ambient and room temperatures. The Elsen et al reference is intended to provide a nondigestible fat composition which when used as a replacement for conventional fats and oils in finished food products effectively eliminates the problem of passive oil loss while maintaining suitable organoleptic properties. The solid portion of the Elsen et al composition, when cooled rapidly under quiescent conditions (without shearing) in accordance with the Elsen disclosure, forms crystallized platelet-like structures that aggregate or cluster together. It is believed that because of their porous nature, these aggregated crystallized platelets bind a portion of the liquid component of the nondigestible fat composition, thereby providing the effective passive oil loss protection.

As the Elsen et al composition is further cooled under quiescent conditions in accordance with the teachings of the Elsen et al reference, the aggregated crystallized platelets connect to each other forming a crystalline matrix that binds the remaining portion of the liquid component of the nondigestible fat composition. This crystalline matrix provides sufficient structure to the nondigestible Elsen composition such that the Elsen nondigestible composition is substantially solid at room and ambient storage temperatures.

Notwithstanding the similarity between the starting components used in the present invention and the components of the Elsen et al reference, the compositions of the present invention are intended to solve a different problem, are prepared using a different method, and have different physical characteristics and properties as a result.

The nondigestible fat compositions of the Elsen et al reference are intended to solve the problem of passive oil loss while maintaining acceptable organoleptic properties. On the other hand, the present compositions would provide little, if any, effective passive oil loss control. The present compositions, of course, do provide passive oil loss control once they are re-melted and crystallized in accordance with Elsen during the preparation or cooling processes for foods containing them.

Rather, the present invention is intended to provide a nondigestible oil composition that prior to its use, is flowable at room or ambient storage temperatures, thereby increasing productivity and safety during the intermediate stages of food production using the nondigestible oil composition.

The nondigestible oil composition of the present invention is made flowable through the application of mechanical shear applied during the cooling process that forms the crystallized particles of requisite size. As the nondigestible compositions herein are cooled during composition formation, a portion of the solid component solidifies into crystallized particles. A portion of these crystallized particles then cluster together forming aggregated crystallized particles. Mechanical shear is applied to the nondigestible composition as cooling continues. The application of mechanical shear encourages the formation of smaller, rather than larger, aggregated crystallized particles by breaking apart the larger aggregations. The application of mechanical shear additionally inhibits the clustering of these aggregated crystallized particles and prevents the formation of the crystalline matrix that gives the nondigestible fat compositions of the Elsen et al reference sufficient structure so as to be substantially solid at room and ambient temperatures.

As the nondigestible oil compositions made in accordance with the present invention do not form a crystalline matrix sufficient to bind the liquid component of the nondigestible compositions the compositions herein remain flowable when cooled to room and ambient storage temperatures. These nondigestible oil compositions will remain flowable during transportation, storage, and use until they are returned to a completely molten state then rapidly cooled under quiescent conditions, such as in the final stages of food or beverage production.

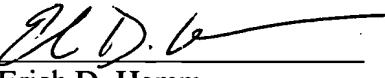
Given the foregoing considerations, it is respectfully submitted that the Elsen et al reference does not teach or obviously suggest the essential elements of Applicant's flowable nondigestible oil compositions or the processes of making the same. Accordingly, rejection of Applicants amended Claims 1-19 and 41-54 over this reference, under 35 USC §103(a) is improper and should be withdrawn.

### Conclusions

Applicants have made an earnest effort to place their application in proper form, to establish the unity of their claimed invention, and to distinguish their claimed invention from the applied prior art. WHEREFORE, reconsideration of this application, withdrawal of the

rejections under 35 U.S.C. §112, First Paragraph, withdrawal of the rejections under 35 U.S.C. §103(a), and allowance of Claims 1-19 and 41-54 are respectfully requested.

Respectfully submitted,  
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**VERSION WITH MARKINGS TO SHOW CHANGES**

Claim 1 has been amended as follows:

1. (Thrice Amended) A flowable nondigestible oil composition comprising a liquid polyol fatty acid polyester having a complete melt point less than 37°C, and a crystallized solid polyol fatty acid polyester having a complete melt point of at least about 37°C, said solid polyol fatty acid polyester comprising a plurality of crystallized spherulites comprising a solid saturated polyol polyester within the liquid polyol fatty acid polyester, wherein particles of said crystallized solid polyol fatty acid polyester have a diameter of from about 1 microns to about 50 microns, and wherein the flowable nondigestible oil composition has a Consistency in a temperature range of 20-40°C [of less than about] in the range of from about 0 P.sec(n-1) to about 30 P.sec(n-1), and wherein the solid polyol fatty acid polyester is crystallized while shearing the nondigestible oil.

Claim 2 has been amended as follows:

2. (Thrice Amended) A flowable nondigestible oil composition comprising a liquid polyol fatty acid polyester having a complete melt point less than 37°C, and a crystallized solid polyol fatty acid polyester having a complete melt point of at least about 37°C, said solid polyol fatty acid polyester comprising a plurality of crystallized spherulites comprising a solid saturated polyol polyester within the liquid polyol fatty acid polyester, wherein particles of said crystallized solid polyol fatty acid polyester have a diameter of from about 1 microns to about 50 microns, and wherein the flowable nondigestible oil composition has a Consistency in a temperature range of 20-40°C [of less than about] in the range of from about 0 P.sec(n-1) to about 30 P.sec(n-1), and wherein the solid polyol fatty acid polyester is crystallized in less than about 5 hours.

Claim 7 has been amended as follows:

7. (Twice Amended) The flowable nondigestible oil composition according to Claim 1 wherein the Consistency in a temperature range of 20°-40°C is [less than about] in the range of from about 0 P.sec(n-1) to about 25 P.sec(n-1).

Claim 8 has been amended as follows:

8. (Twice Amended) The flowable nondigestible oil composition according to Claim 3 wherein the Consistency in a temperature range of 20°-40°C is [less than about] in the range of from about 0 P.sec(n-1) to about 20 P.sec(n-1).

Claim 9 has been amended as follows:

9. (Twice Amended) The flowable nondigestible oil composition according to Claim 7 wherein the Consistency in a temperature range of 20°-40°C is [less than about] in the range of from about 0 P.sec(n-1) to about 20 P.sec(n-1).

Claim 10 has been amended as follows:

10. (Twice Amended) The flowable nondigestible oil composition according to Claim 8 wherein the Consistency in a temperature range of 20°-40°C is [less than about] in the range of from about 0 P.sec(n-1) to about 10 P.sec(n-1).

Claim 11 has been amended as follows:

11. (Twice Amended) The flowable nondigestible oil composition according to Claim 9 wherein the Consistency in a temperature range of 20°-40°C is [less than about] in the range of from about 0 P.sec(n-1) to about 10 P.sec(n-1).

Claim 41 has been amended as follows:

41. (Thrice Amended) A flowable nondigestible oil composition comprising a liquid polyol fatty acid polyester having a complete melt point of a less than about 37°C, and a solid polyol fatty acid polyester having a complete melt point of at least about 37°C, wherein the solid polyol fatty acid polyester is in the form of crystallized spherulitic particles, wherein said crystallized spherulitic particles have a diameter of from about 1 microns to about 50 microns, and wherein the flowable nondigestible oil composition has a Consistency in a temperature range of 20-40°C [of less than about] in the range of from about 0 P.sec(n-1) to about 30 P.sec(n-1).

Claim 42 has been amended as follows:

42. (Twice Amended) The flowable nondigestible oil composition according to Claim 41 wherein the Consistency is [less than about] in the range of from about 0 P.sec<sup>(n-1)</sup> to about 25 P.sec<sup>(n-1)</sup>.